APR 2 5 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: _____

1. Submitter Information

1.1 Submitter's Identification:

Company Name:	FORA CARE INC.
Contact Person:	Sophia Wu
Title:	CEO
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1.2 Correspondence:

Contact Person:	Sharon Peng
Title:	Regulatory Affairs Specialist
Phone:	+886-2-6625-8188 #1176
Fax:	+886-2-6625-0288
E-mail:	sharon_peng@taidoc.com.tw
Prepared Date:	November 15th, 2013

2. Device name:

Trade/Proprietary Name:	Fora Care Blood Pressure Monitoring System
Common Name:	Blood Pressure Monitor/Measurement
Model Number:	P80
Product Code:	DXN
Classification Panel:	74, Cardiovascular
Classification:	Class II
Regulation Section:	21 CFR §870.1130, Non-invasive Blood Pressure Measurement System

3. Predicate Device

Trade/Proprietary Name:	U-RIGHT TD-3128 Blood Pressure Monitoring System
Common/Usual Name:	Blood Pressure Test System
510(k) Number:	K112216

4. Intended Use

Fora Care Blood Pressure Monitoring System is a system designed to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. It is intended for individuals age 18 and above use at home and in clinical settings.

The device is not to be used for the diagnosis of hypertension or for testing on newborns.

5. Device Description:

Fora Care Blood Pressure Monitoring System (Model: P80) can be operated by the device itself or with the TDLink BP App. TDLink BP App is designed to assist in blood pressure testing, recording, tracking and monitoring in easy.

6. Test Principle:

Fora Care Blood Pressure Monitoring System is measured non-invasively at the arm based on oscillometric method.

This device is not able to take measurements in the presence of common arrhythmia, such as atrial or ventricular premature beats or atrial fibrillation. It may produce reading error.

7. Substantial Equivalence Information:

Predicate device name:	U-RIGHT TD-3128 Blood Pressure Monitoring System
Predicate K number:	K112216
Comparison with predicate:	The modified Fora Care Blood Pressure Monitoring System has the following similarities to the predicate device: ■ same intended use,

	■ same operating principle, ■ same fundamental scientific technology, ■ incorporate the same basic circuit design, ■ incorporate the same materials, ■ same shelf-life, ■ packaged using the same materials, and ■ manufactured by the same process. The modifications encompass: ■ Linkage with TDLink BP App ■ Remove irregular heart rate detection ■ Without meter memory ■ Modification of the devices physical appearance ■ Labeling change due to the above modifications

The Fora Care Blood Pressure Monitoring System and the predicate device both use the oscillometric method within the software algorithm to determine the systolic, diastolic blood pressure and pulse rate with an inflatable arm cuff.

The major difference between the two devices is the application of TDLink BP App and physical appearance of device. The minor software change enables the device to connect with TDLink BP App in personal mobile. The memory unction of meter itself and irregular heart rate detection are removed. User may use the compatible TDLink BP App and review the test results on personal mobile.

8. Performance Characteristics:

A blood pressure accuracy testing was performed to demonstrate the Fora Care Blood Pressure Monitoring System meets the same performance specifications as the predicate device. And the accuracy has been demonstrated in the predicate 510(k) submission according to the requirements of ANSI/AAMI SP10:2002. No clinical study was performed using the subject device since the subject device's blood pressure monitoring capability was duplicated from the predicate, K11216 submitted by TaiDoc.

Software validation was performed to verify and validate the system works functionally.

Testing performed included electrical safety, EMC, and shock and vibration test. The proposed device met the requirements of IEC/EN 60601-1, IEC/EN 60601-1-2 and IEC/EN 60601-1-11.

Biocompatibility testing was also performed. The materials of cuff met the requirements of ISO 10993-5 and 10993-10.

The Fora Care Blood Pressure Monitoring System has the same performance characteristics as the predicate device. Software verification and validation, and design validation confirmed that the performance, safety and effectiveness of the Fora Care Blood Pressure Monitoring System are substantial equivalent to the predicate device.

9. Conclusion:

Based on the information provided in this submission, the Fora Care Blood Pressure Monitoring System is substantially equivalent to the predicate U-RIGHT TD-3128 Blood Pressure Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Fora Care Inc.
c/o Ms. Sharon Peng, Regulatory Affairs Specialist
TaiDoc Technology Corporation
6F, No. 127, Wugong 2nd Road, Wugu District
New Taipei City 24888
TAIWAN

Re: K133588
Trade/Device Names: Fora Care Blood Pressure Monitoring System, Model P80
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: March 15, 2014
Received: March 19, 2014

Dear Ms. Peng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

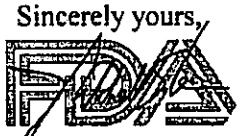
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K133588

Device Name: Fora Care Blood Pressure Monitoring System

Indications for Use:

Fora Care Blood Pressure Monitoring System is a system designed to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. It is intended for individuals age 18 and above use at home and in clinical settings. The device is not to be used for the diagnosis of hypertension or for testing on newborns.

Prescription Use _____ And/Or Over the Counter Use __X__.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Date: 2014.04.25 14:46:01 -04'00'

Division Sign-Off
Office of Device Evaluation (ODE)
510(k)_____